IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| THE PROCTER & GAMBLE CO., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant. | ) | C.A. No. 04-940-JJF |

**DEFENDANT TEVA PHARMACEUTICALS USA, INC.'S OPPOSITION TO PLAINTIFF PROCTER & GAMBLE CO.'S REQUEST FOR ENTRY OF JUDGMENT**

The Court ordered P&G to submit a proposed final judgment order with notice to Teva USA. *See* D.I. 118. P&G refused Teva USA's suggestion to confer in advance in order to avoid unnecessary waste of the Court's time. Instead, on March 13, P&G submitted a proposed Order of Final Judgment that is obviously contrary to law. *See* attachment to D.I. 119. Specifically, P&G's judgment includes two major deficiencies: (1) it states that the litigated claims are "valid" and "enforceable"; and (2) it grants injunctive relief that the Court may not enter under the patent laws.

## I. THE COURT SHOULD NOT DECLARE THE '122 PATENT "VALID" OR "ENFORCEABLE"

P&G's proposed judgment states that claims 4, 16, and 23 of the '122 patent are "valid." The case involved Teva USA's challenge to the validity of those claims, and the Court held that that challenge did not succeed. That holding, however, does not mean that the claims are "valid." The Federal Circuit long ago recognized the distinction, and held that a court should not declare a patent claim "valid":

> [i]t is neither necessary nor appropriate for a court to declare a patent valid. A trial court is required by Congress, 35 U.S.C. § 282 . . . to say only whether the

> patent challenger carried its burden of establishing invalidity in the particular case before the court. . . . It is the judiciary's duty to follow statutes that requires a trial court lacking a conviction of obviousness to hold that the challenger's burden was not carried. Thereupon, the patent simply remains valid until another challenger carries the § 282 burden.

*Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1569–70 (Fed. Cir. 1987). Entering a judgment that declares the '122 patent valid would therefore be contrary to law.

Not only does P&G ask that its patent claims be adjudicated "valid," it asserts that they should be adjudicated "enforceable." That issue, however, was not litigated in this action. Since the record contains no basis on which to predicate a judgment that the claims are "enforceable," the Court should not enter such a judgment.

## II. THE COURT SHOULD NOT ENTER THE REQUESTED JUDGMENT BECAUSE IT GRANTS INJUNCTIVE RELIEF NOT PERMITTED BY THE PATENT LAWS

### A. The Court Cannot Order the FDA Not to Approve Teva USA's ANDA after the '122 Patent Expires

Because this is an ANDA case, the Court may order two separate forms of injunctive relief. The first relates to the approval of Teva USA's ANDA, and is set forth in 35 U.S.C. § 271(e)(4)(A):

> the court shall order the effective date of any approval of the drug . . . involved in the infringement to be a date which is not earlier than the date of the expiration of the patent which has been infringed.

Although P&G's form of judgment prohibits the FDA from approving the ANDA until the end of the patent term, it also prohibits the FDA from approving the ANDA until the "expiration of the '122 patent, *including any extensions and regulatory exclusivities* that are granted and not successfully challenged." (Emphasis added). Nowhere does the judgment say what "extensions and regulatory exclusions" P&G has in mind. First, the '122 patent has never been extended and is not eligible for any extension. Second, this Court does not have the

authority to implement "regulatory exclusivities" under the patent laws or under any other statute. Accordingly, the Court should not enter P&G's proposed injunction.

**1. P&G Cannot Extend the '122 Patent**

The only "extension" of a patent term pertinent here is governed by 35 U.S.C. § 156, which permits the Patent Office to extend a patent term in certain cases in which the marketing of the patented product was held up by regulatory action, e.g., by the FDA. That statute, however, requires that the application for the extension be filed within sixty days of the first marketing of the product, which P&G did not do. *See* 35 U.S.C. § 156(d)(1). Moreover, since the remaining term of the patent was more than 14 years at the time the FDA first approved risedronate, the '122 patent is ineligible for an extension in any event. *See* section 156(c)(3).[1] Accordingly, since the '122 patent term is not extendable, the injunction should not refer to "extensions."

**2. P&G Is Not Entitled to an Injunction to Enforce Regulatory Exclusivities**

P&G seeks an injunction order preventing the FDA from approving Teva USA's ANDA until after the expiration of P&G's unspecified "regulatory exclusivities." The only potentially applicable regulatory exclusivities to which P&G's proposal could apply are not governed by the patent statute, but instead are creatures of the food and drug laws. The broadest such exclusivity is what is called a "pediatric exclusivity," by which the FDA will defer the approval of an ANDA for six months beyond the expiration of the listed patent (here, the '122 patent) if the NDA holder (here, P&G), submits data showing that the drug is safe and effective for pediatric use. *See* 21 U.S.C. § 355A(c)(2)(B). P&G apparently has not yet submitted such data for risedronate, but if it does, and if the validity of the '122 patent is not successfully challenged

[1] The first FDA approval for risedronate was in 1998, and the patent expires in 2013.

before the patent expires, the FDA will automatically delay any ANDA approval for six months after the patent expiration date.

The pediatric exclusivity is a statutory restriction that applies to certain actions by the FDA. Although the pediatric exclusivity is tacked on to the patent term, it is not a patent right. The existence of the patent simply provides a date from which to measure the exclusivity. The law is clear that an injunction granted under the patent laws is restricted in scope to the rights granted by a patent. *Eli Lilly & Co. v. Medtronic, Inc.*, 915 F.2d 670, 674 (Fed. Cir. 1990) ("an injunction is only proper to the extent it is 'to prevent the violation of any right secured by patent'"); *see also Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770 (Fed. Cir. 1993). An FDA-mandated restriction on Teva USA's ability to market the drug after the patent expires is not "secured by patent." It is separate and apart from any issue litigated in this case. For that reason, the Court does not have discretion to enjoin the FDA from approving Teva USA's ANDA once the '122 patent expires.

In addition to the pediatric exclusivity, the FDA may also grant other exclusivities based on P&G's obtaining FDA approval for, e.g., a new indication for the drug that is already on the market. *See* 21 U.S.C. §§ 355(j)(5)(F)(iii) and (iv) (three-year exclusivity if new approval required "new clinical investigation").[2] The statute makes clear that such an exclusivity only applies to the new indication, and would not apply for the previously-approved indications (in this case, prevention and treatment of osteoporosis and treatment of Paget's disease). The existence of such an exclusivity, therefore, does not preclude approval of an otherwise approvable ANDA for those previously-approved indications. Under P&G's proposed

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[2] The same kind of exclusivity applies to newly approved dosage regimens, new formulations, and new patient populations – as long as the approval required the NDA holder to submit data from a "new clinical investigation."

injunction, however, if P&G obtained a new indication exclusivity that extended beyond the patent term (or beyond the pediatric exclusivity), the FDA could not approve Teva USA's ANDA even for the previously-approved uses. Teva USA's competitors, on the other hand, would not be subject to such restrictions. Upon the expiration of the patent (or the pediatric exclusivity), the FDA could approve their ANDAs for those previously-approved indications. P&G's proposed injunction would place Teva USA at a disadvantage with respect to its competitors in that Teva USA could not market its product for the old indications, but all its competitors would be legally free to do so. Thus, the injunction would be punitive rather than remedial. The entry of such an injunction is beyond the Court's discretion. *See Joy Techs.*, 6 F.3d at 777 (vacating injunction that placed defendant in a different position from lawful competitors and was therefore punitive).

### B. The Court Cannot Enjoin Teva USA Beyond the Term of the '122 Patent

The patent statute permits the Court to enjoin Teva USA's commercial activities with respect to the patented product:

> injunctive relief may be granted against an infringer to prevent the commercial manufacture, use, offer to sell, or sale, within the United States or importation into the United States of an approved drug. . . .

35 U.S.C. § 271(e)(4)(B). Like its proposed injunction with respect to FDA approval of Teva USA's ANDA, P&G's proposed injunction with respect to Teva USA's commercial activities goes too far. Not only would it enjoin Teva USA for the life of the '122 patent, it would enjoin all commercially related activities during any period of FDA exclusivity that extends beyond the patent term:

> Teva . . . [is] hereby enjoined from commercially making, using, offering to sell or selling, within the United States, or importing into the United States any products that infringe the '122 patent, ...until the ***later*** of the expiration of the

> '122 patent (December 10, 2013) or the expiration of any patent term extensions or any regulatory exclusivities that are granted and not successfully challenged.

(Emphasis in original). Specifically, P&G's proposed injunction would prohibit Teva USA from "making" or "importing" its generic products after the patent expires, even though no FDA exclusivity could prevent Teva USA from carrying out these activities. The broadest such exclusivity, the pediatric exclusivity, only precludes the FDA from approving an ANDA. *See* 21 U.S.C. § 355A(c)(2)(B): "the period during which the application may not be approved . . . shall be extended by a period of six months after the date the patent expires. . . ." The statute thus restricts what the FDA can do, but imposes no restrictions on the ANDA applicant, and therefore would not prohibit Teva USA from "making" or "importing" the product during the exclusivity period. Under P&G's proposal, however, after the patent expires, Teva USA could not make or import generic risedronate, but every other generic producer of risedronate except Teva USA would be free to do so, and to have it ready for launch when the pediatric exclusivity expired, because neither the patent nor the exclusivity would preclude such activities. Again, P&G's proposal would place Teva USA at a competitive disadvantage, and its entry would therefore be outside the Court's discretion.

The same disparity would exist with respect to any other regulatory exclusivity. If P&G were to obtain an indication exclusivity that extends beyond the patent term, under its proposal every competitor except Teva USA would be free to market risedronate for the previously-approved indications, and Teva USA would therefore be placed at a competitive disadvantage. Again, such an injunction is punitive rather than remedial, and is beyond the Court's discretionary authority. *Joy Techs.*, *supra.*

P&G's proposed judgment is contrary to law and grants P&G relief to which it is not entitled. It should not be entered.

## III. TEVA USA'S PROPOSED JUDGMENT SHOULD BE ENTERED

Teva USA has proposed a form of judgment that is in accordance with the patent laws, and that protects all the rights that P&G has under the '122 patent. Teva USA's proposal is attached as Exhibit A. It adjudicates exactly what the parties litigated: the validity of claims 4, 16 and 23 of the '122 patent. The language of the injunction provisions mirrors that of 35 U.S.C. §§ 271(e)(4)(A) and (B), which is all the relief that Congress intended that a prevailing patentee receive in a case under the Hatch-Waxman Act. Accordingly, Teva USA respectfully submits that its proposal should be entered.

**YOUNG CONAWAY STARGATT & TAYLOR LLP**

*/s/ Karen L. Pascale*

March 20, 2008

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**CERTIFICATE OF SERVICE**

I, Karen L. Pascale, Esquire, hereby certify that on March 20, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following non-registered participants in the manner indicated:

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